

## Food and Drug Administration, HHS

## § 1002.20

has acted or is acting in compliance with the Act and any standards prescribed thereunder, and to enable the Director to carry out the purposes of the Act.

[60 FR 48386, Sept. 19, 1995, as amended at 72 FR 17400, Apr. 9, 2007]

### § 1002.11 Supplemental reports.

Prior to the introduction into commerce of a new or modified model within a model or chassis family of a product listed in table 1 of § 1002.1 for which a report under § 1002.10 is required, each manufacturer shall submit a report with respect to such new or modified model describing any changes in the information previously submitted in the product report. Reports will be required for changes that:

(a) Affect actual or potential radiation emission.

(b) Affect the manner of compliance with a standard or manner of testing for radiation safety.

### § 1002.12 Abbreviated reports.

Manufacturers of products requiring abbreviated reports as specified in table 1 of § 1002.1 shall submit, prior to the introduction of such product, a report distinctly marked "Radiation Safety Abbreviated Report" which shall include:

(a) Firm and model identification.

(b) A brief description of operational characteristics that affect radiation emissions, transmission, or leakage or that control exposure.

(c) A list of applications or uses.

(d) Radiation emission, transmission, or leakage levels.

(e) If necessary, additional information as may be requested to determine compliance with the Act and this part.

### § 1002.13 Annual reports.

(a) Every manufacturer of products requiring an annual report as specified in table 1 of § 1002.1 shall submit an annual report summarizing the contents of the records required to be maintained by § 1002.30(a) and providing the volume of products produced, sold, or installed.

(b) Reports are due annually by September 1. Such reports shall cover the 12-month period ending on June 30 preceding the due date of the report.

(c) New models of a model family that do not involve changes in radiation emission or requirements of a performance standard do not require supplemental reports prior to introduction into commerce. These model numbers should be reported in quarterly updates to the annual report.

## Subpart C—Manufacturers' Reports on Accidental Radiation Occurrences

### § 1002.20 Reporting of accidental radiation occurrences.

(a) Manufacturers of electronic products shall, where reasonable grounds for suspecting that such an incident has occurred, immediately report to the Director, Center for Devices and Radiological Health, all accidental radiation occurrences reported to or otherwise known to the manufacturer and arising from the manufacturing, testing, or use of any product introduced or intended to be introduced into commerce by such manufacturer. Reasonable grounds include, but are not necessarily limited to, professional, scientific, or medical facts or opinions documented or otherwise, that conclude or lead to the conclusion that such an incident has occurred.

(b) Such reports shall be addressed to the Center for Devices and Radiological Health, ATTN: Accidental Radiation Occurrence Reports (HFZ-240), Office of Communication, Education, and Radiation Programs, 9200 Corporate Blvd., Rockville, MD 20850, and the reports and their envelopes shall be distinctly marked "Report on 1002.20" and shall contain all of the following information where known to the manufacturer:

(1) The nature of the accidental radiation occurrence;

(2) The location at which the accidental radiation occurrence occurred;

(3) The manufacturer, type, and model number of the electronic product or products involved;

(4) The circumstances surrounding the accidental radiation occurrence, including causes;

(5) The number of persons involved, adversely affected, or exposed during the accidental radiation occurrence,